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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,540	09/22/2003	Lawrence M. Boyd	1842-0024	9957
28078 7590 07/11/2008 MAGINOT, MOORE & BECK, LLP CHASE TOWER 111 MONUMENT CIRCLE SUITE 3250 INDIANAPOLIS, IN 46204			EXAMINER PHILOGENE, PEDRO	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 07/11/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,540	Applicant(s) BOYD ET AL.	
	Examiner Pedro Philogene	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-40,42-47,49,51-65,69-72,80-82 and 84-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-40,42-47,49,51-65,69-72,80-82 and 84-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/18/08,6/25/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 85-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 85, line 7, the term "the distal tip" lacks prior antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-40, 42-47, 49, 51-65, 69-72, 80-82, 84, 90-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox (6,018,094) in view of Felt et al (5,888,220).

Fox discloses a kit of parts and a device for sealably introducing fluent material directly into a space through an opening (13, 15) extending through portion of bone (12) comprising: a seal (19,27) for cooperatively engaging the bone (12) adjacent the opening (13,15) for sealing the opening, the seal includes a sealing element (19,27) disposed in the lumen, the seal includes a cannula (28) separate from the tube (31,32,33) the cannula having an interior lumen through which the tube extends in use, as best seen in Fig.6, the exterior of the cannula being configured to securely fit into the

Art Unit: 3733

opening, the distal end of the cannula is defined by an insertion tip, as best seen in FIG.6, configured for facilitating entry into the opening, the seal is disposed on the insertion tip, the insertion tip is capable of engaging endplates of opposing vertebrae into the opening, a tube (31,32,33) having a passageway, as best seen in FIG.6, for the flow of fluent material therethrough, the tube being configured for cooperative sealed engagement through the seal, as best seen in FIG.6; and a quantity of curable fluent material (322) adapted to be introduced in a fluid state into the space through the passageway of the tube; a vent (33) separate from the tube extending through the seal in sealed engagement therewith and in direct communication with the disc space when the seal engages the bone; as best seen in FIG.6., the extent defining a vent (33) as best seen in FIG.6, separate from the tube and adjacent the tube and arranged to communicate with the opening.

it is noted that in a similar art, Felt et al provide the evidence of the use of introducing fluent material directly into the disc space through an opening extending through the annulus fibrosis of a disc, comprising a tube having a passage way for the flow of fluent material therethrough and an extent adapted to be received in the opening of the annulus fibrosis, a quantity of curable of curable fluent material adapted to be introduced in a fluid state into the disc space through the passageway of the tube, the material upon curing having properties substitutive of the nucleus pulposus and distract two opposing vertebrae and introduce under pressure a curable material through the opening contiguously, as set forth in column 4, lines 54, in the distracted

opening to cure the biomaterial in situ in order to repair and replace the intervertebral disc of the spine.

Therefore, given the teaching of Fox, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Felt et al, as taught by Fox to sealably introduce the biomaterial in the distracted opening to cure the biomaterial in situ in order to repair and replace the intervertebral disc of the spine.

With respect to the method claims, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above. The method steps, such as, creating an opening through the disc annulus fibrosis; distracting the vertebral bodies apart to increase disc height, introducing under pressure a curable biomaterial having properties substitutive of nucleus pulposus when cured through the opening contiguously into the intradiscal space until the intradiscal space is substantially filled are fully disclosed by Felt et al; in column 4, lines 39-55, 59-67, column 5, lines 1-47, column 6, lines 29-67.

With regard to the recitation that an element is “configured to” or “configured for”, it is noted that it has been held that the recitation that an element is “configured for “ or “configured to” perform a function is not a positive limitation but requires the ability to so perform. It does not constitute a limitation in any patentable sense. In addition, the manner in which a device is intended to be employed, does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitation. *Ex parte Masham*, 2 USQ2d 1647 (1887).

As to the limitation that the seal is separate or integral with the cannula, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177,179 or it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Allowable Subject Matter

Claims 85-89 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Amendment

Applicant's arguments, see Remarks, filed 4/18/08, with respect to the rejection(s) of claim(s) 34-40, 42-47, 49, 51-65, 69-72, 80-97 under 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Fox/Felt et al. Fox discloses a seal, a tube and a vent separate from the tube for introducing fluent material to an opening in the cortical bone. Felt discloses a device for introducing fluent material directly into a disc space through an opening formed through the annulus fibrosis of the disc. Therefore, combining the device of Fox with the device of Felt et al to arrive at applicant's claimed invention would have been obvious to one of ordinary skill in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/
Primary Examiner, Art Unit 3733
July 09, 2008